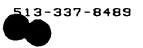
7



#### REMARKS

Claims 46, 50, and 56 were rejected as anticipated, and Claims 47-49, 51-55, and 57-59 were rejected as obvious in the Examiner's office action. Claims 46-50 and 56-59 are cancelled without prejudice, and Applicant reserves the right to file a continuation application with respect to the cancelled claims.

Claims 60-73 are added.

Claims 51-55 and 60-73 remain pending. Four independent claims and 19 total claims are pending.

Support for the added claims is found in the specification and drawings. No new matter is added. For example, but with out limitation:

With respect to Claim 60, support for a plurality of markers disposed in the lumen proximal of the side exit can be found in Figure 16 and page 21, lines 5-23, and support for recitation of an element disposed in the lumen for pushing markers is found in Figure 12 and page 18, lines 1-5, lines 24-30, and page 19 lines 1-7.

With respect to Claim 61, 62, 63, 65, 70, and 71, support is found at page 9, lines 14-25 and page 23, lines 2-6.

With respect to Claim 64, support is found in Figures 4-8, page 7 lines 4-11 and page 13, line 27 to page 14, line10.

With respect to Claims 66 and 69, support is found in Figure 16, and page 21, lines 5-23.

With respect to Claim 67, 68, 72, and 73, support is found at page 21, lines 16-23, page 22, lines 7-19, and Figures 13-20.

#### Supplemental IDS:

The Examiner is requested to consider and make of record the information disclosure statement submitted May 1, 2003.



## Claim Rejections:

#### 112 Rejection

The claims rejected under 35 USC 112 have been cancelled without prejudice, and withdrawal of the rejection is requested.

### 102 rejection

The claims rejected by the Examiner as anticipated have been cancelled without prejudice, and withdrawal of the rejection is requested.

# Kaldany '613 applied as 102(b) reference

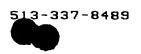
The Examiner is respectfully requested to clarify how Kaldany 613 with a publication date of Oct 8, 1996 (priority dates of Oct. 23, 1992, July 6, 1992, and Jul 6, 1994) is a 102(b) reference with respect to the present application, which claims priority to 08/858389 filed May 19, 1997, which claims priority to 08/308,097 filed September 16, 1994.

## 103 Rejection

Claims 51-55 are rejected as obvious over Kaldany 613 in view of US 4,709,703 to Lazarow et al. (Lazarow). It is respectfully urged that this rejection is improper for at least the following reasons.

### No Prima Facie Case

A prima facie case of obviousness requires that there be some suggestion or motivation (either in the references themselves or in the knowledge generally available to one of ordinary skill in the art) to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed



combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (MPEP 2142).

## No Motivation to Combine:

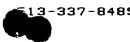
It is respectfully urged that one would not be motivated to combine Kaldany and Lazarow as suggested by the Examiner. Kaldany discloses a subcutaneous drug delivery device (see column 2, lines 45-49). Lazarow is directed to measurement of organ tissue perfusion and disbursement of blood throughout the body. (see column 2, lines 65-68). The examiner is respectfully urged to clarify why one would look to a reference regarding organ tissue perfusion and blood disbursement to modify a subcutaneous drug delivery device.

It is also respectfully urged that the Examiner has mischaracterized Kaldany in combining the references. The Examiner considers the drug pellet 106 to be a marker for purposes of combining the references. The Examiner is respectfully requested to clarify what portion of Kaldany teaches or suggests use of drug pellet 106 as a tissue marker.

Additionally, the Examiner acknowledges Kaldany does not disclose a plurality of discrete marker elements. The Examiner states it would be obvious to one having ordinary skill in the art at the time the invention was made to replace the marker of Kaldany for the markers of Lazarow in order to provide an imaging procedure that did not require a second surgery. However, the Examiner's reational assumes that there would be some motivation to provide imaging in the case of Kaldany's drug delivery device in the first place. The Examiner is respectfully requested to clarify why one would desire imaging in the case of a drug delivery device of Kaldany.

Moreover, the Examiner's basis for the rejection seems to imply that requirement for a second surgery would be an issue in the case of the Kaldany device. It is respectfully urged that it is not clear why one would be concerned about a second surgery in the case of the Kaldany device. Clarification is requested.





'It is respectfully urged that the Examiner has improperly relied on the Applicants' disclosure in hindsight. The Examiner is requested to provide motivation in the prior art for the combination suggested by the Examiner.

# Combination, If Made, Would Not Teach Invention:

It is respectfully urged that even if one were to combine the references as suggest by the Examiner, the combination would not teach all the claim limitations.

For instance, with respect to added claim 60, the combination would not teach a plurality of tissue markers disposed in a lumen proximal to a side exit port. With respect to added Claim 72, the combination would not teach at least one marker having a size different from one of the other markers. With respect to added Claim 73, the combination would not teach at least one marker having a shape different from one of the other markers.

### Conclusion:

The Examiner is respectfully urged to reconsider and allow the pending claims.

Respectfully,

Gerry Gressel, Reg. 34,342

June 13, 2003

Johnson & Johnson

Patent Department

One Johnson & Johnson Plaza

New Brunswick, NJ 08933